



ARIZONA DEPARTMENT OF ENVIRONMENTAL QUALITY

AIR QUALITY CLASS II PERMIT

COMPANY: *STERIS, Inc*
FACILITY: *Ethylene Oxide Sterilization Facility*
PERMIT #: *34304*
DATE ISSUED: *Draft*
EXPIRY DATE:

SUMMARY

This Class II renewal permit is issued to STERIS, Inc. the Permittee, for operation of their Ethylene Oxide Sterilization Facility located at 1350 North Industrial Park Drive, Nogales, Arizona.

Steris, Inc. operates a sterilization facility which utilizes ethylene oxide (ETO) to sterilize medical products. The sterilization facility consists of two 26 pallet Vacu-dyne sterilization chambers, four individually controlled pre-conditioning rooms, and an aeration chamber consisting of four individually controlled Degas hot cells (aeration room), and an ETO storage and weigh room.

The facility operates two counterflow DEOXX scrubbers systems and a catalytic oxidizer system to reduce the ETO emissions from the sterilizers and the aeration chamber degas cells. The catalytic oxidizer is equipped with a natural gas fired heater. Two natural gas fired boilers provide the required humidity and heat to the Vacu-dyne vessels. A water heater provides hot water for heat exchange in the ETO warehouse.

In this renewal action, Steris, Inc. has been authorized to increase the ETO charge per cycle from 250 lbs to 400 lbs, and also increase the number of sterilization cycles from 2 per day to 3 per day. These changes will result in an annual usage of 438 tons of ETO per year.

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ATTACHMENT “A”: GENERAL PROVISIONS

Air Quality Control Permit No. 34304

STERIS, Inc.

I. PERMIT EXPIRATION AND RENEWAL

[ARS § 49-426.F, A.A.C. R18-2-304.C.2, and -306.A.1]

- A.** This permit is valid for a period of five years from the date of issuance.
- B.** The Permittee shall submit an application for renewal of this permit at least 6 months, but not more than 18 months, prior to the date of permit expiration.

II. COMPLIANCE WITH PERMIT CONDITIONS

[A.A.C. R18-2-306.A.8.a and b]

- A.** The Permittee shall comply with all conditions of this permit including all applicable requirements of the Arizona air quality statutes and air quality rules. Any permit noncompliance constitutes a violation of the Arizona Revised Statutes and is grounds for enforcement action; for permit termination, revocation and reissuance, or revision; or for denial of a permit renewal application. In addition, noncompliance with any federally enforceable requirement constitutes a violation of the Clean Air Act.
- B.** It shall not be a defense for a Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

III. PERMIT REVISION, REOPENING, REVOCATION AND REISSUANCE, OR TERMINATION FOR CAUSE

[A.A.C. R18-2-306.A.8.c, -321.A.1, and -321.A.2]

- A.** The permit may be revised, reopened, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a permit revision, revocation and reissuance, termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit condition.
- B.** The permit shall be reopened and revised under any of the following circumstances
 - 1.** Additional applicable requirements under the Clean Air Act become applicable to the Class I source. Such a reopening shall only occur if there are three or more years remaining in the permit term. The reopening shall be completed no later than 18 months after promulgation of the applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which the permit is due to expire, unless an application for renewal has been submitted pursuant to A.A.C. R18-2-322.B. Any permit revision required pursuant to this subparagraph shall comply with the provisions in A.A.C. R18-2-322 for permit renewal and shall reset the five-year permit term.
 - 2.** Additional requirements, including excess emissions requirements, become applicable to an affected source under the acid rain program. Upon approval by the Administrator, excess emissions offset plans shall be deemed to be incorporated into the Class I permit.
 - 3.** The Director or the Administrator determines that the permit contains a material mistake or that inaccurate statements were made in establishing the emissions standards or other terms or conditions of the permit.

4. The Director or the Administrator determines that the permit needs to be revised or revoked to assure compliance with the applicable requirements.
- C. Proceedings to reopen and reissue a permit, including appeal of any final action relating to a permit reopening, shall follow the same procedures as apply to initial permit issuance and shall, except for reopenings under Condition III.B.1 above, affect only those parts of the permit for which cause to reopen exists. Such reopenings shall be made as expeditiously as practicable. Permit reopenings for reasons other than those stated in Condition III.B.1 above shall not result in a resetting of the five-year permit term.

IV. POSTING OF PERMIT

[A.A.C. R18-2-315]

- A. The Permittee shall post this permit or a certificate of permit issuance where the facility is located in such a manner as to be clearly visible and accessible. All equipment covered by this permit shall be clearly marked with one of the following:
1. Current permit number; or
 2. Serial number or other equipment ID number that is also listed in the permit to identify that piece of equipment.
- B. A copy of the complete permit shall be kept on site.

V. FEE PAYMENT

[A.A.C. R18-2-306.A.9 and -326]

The Permittee shall pay fees to the Director pursuant to ARS § 49-426(E) and A.A.C. R18-2-326.

VI. ANNUAL EMISSION INVENTORY QUESTIONNAIRE

[A.A.C. R18-2-327.A and B]

- A. The Permittee shall complete and submit to the Director an annual emissions inventory questionnaire. The questionnaire is due by March 31st or ninety days after the Director makes the inventory form available each year, whichever occurs later, and shall include emission information for the previous calendar year.
- B. The questionnaire shall be on a form provided by the Director and shall include the information required by A.A.C. R18-2-327.

VII. COMPLIANCE CERTIFICATION

[A.A.C. R18-2-309.2.a, -309.2.c-d, and -309.5.d]

- A. The Permittee shall submit a compliance certification to the Director semiannually, which describes the compliance status of the source with respect to each permit condition. The first certification shall be submitted no later than May 15th, and shall report the compliance status of the source during the period between October 1st of the previous year and March 31st of the current year. The second certification shall be submitted no later than November 15th, and shall report the compliance status of the source during the period between April 1st and September 30th of the current year.

The compliance certifications shall include the following:

1. Identification of each term or condition of the permit that is the basis of the certification;
 2. Identification of the methods or other means used by the Permittee for determining the compliance status with each term and condition during the certification period, and whether the methods or other means provide continuous or intermittent data;
 3. The status of compliance with the terms and conditions of the permit for the period covered by the certification, including whether compliance during the period was continuous or intermittent. The certification shall be based on the methods and means designated in Condition VII.A.2 above. The certifications shall identify each deviation and take into account for consideration in the compliance certification;
 4. The status of compliance with the terms and conditions of this permit for the period covered by the certification, based on the methods or means designated in Condition VII.A.2 above. The certifications shall identify each deviation and take it into account for consideration in the compliance certification;
 5. For emission units subject to 40 CFR Part 64, the certification shall also identify as possible exceptions to compliance any period during which compliance is required and in which an excursion or exceedance defined under 40 CFR Part 64 occurred;
 6. All instances of deviations from permit requirements reported pursuant to Condition XII.B of this Attachment; and
 7. Other facts the Director may require to determine the compliance status of the source.
- B.** A copy of all compliance certifications shall also be submitted to the EPA Administrator.
- C.** If any outstanding compliance schedule exists, a progress report shall be submitted with the semi-annual compliance certifications required in Condition VII.A above.

VIII. CERTIFICATION OF TRUTH, ACCURACY AND COMPLETENESS

[A.A.C. R18-2-304.H]

Any document required to be submitted by this permit, including reports, shall contain a certification by a responsible official of truth, accuracy, and completeness. This certification shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

IX. INSPECTION AND ENTRY

[A.A.C. R18-2-309.4]

Upon presentation of proper credentials, the Permittee shall allow the Director or the authorized representative of the Director to:

- A.** Enter upon the Permittee's premises where a source is located, emissions-related activity is conducted, or where records are required to be kept under the conditions of the permit;
- B.** Have access to and copy, at reasonable times, any records that are required to be kept under the conditions of the permit;

- C. Inspect, at reasonable times, any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under the permit;
- D. Sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with the permit or other applicable requirements; and
- E. Record any inspection by use of written, electronic, magnetic and photographic media.

X. PERMIT REVISION PURSUANT TO FEDERAL HAZARDOUS AIR POLLUTANT STANDARD

[A.A.C. R18-2-304.C]

If this source becomes subject to a standard promulgated by the Administrator pursuant to Section 112(d) of the Act, then the Permittee shall, within twelve months of the date on which the standard is promulgated, submit an application for a permit revision demonstrating how the source will comply with the standard.

XI. ACCIDENTAL RELEASE PROGRAM

[40 CFR Part 68]

If this source becomes subject to the provisions of 40 CFR Part 68, then the Permittee shall comply with these provisions according to the time line specified in 40 CFR Part 68.

XII. EXCESS EMISSIONS, PERMIT DEVIATIONS, AND EMERGENCY REPORTING

A. Excess Emissions Reporting

[A.A.C. R18-2-310.01.A and -310.01.B]

1. Excess emissions shall be reported as follows:

- a. The Permittee shall report to the Director any emissions in excess of the limits established by this permit. Such report shall be in two parts as specified below:
 - (1) Notification by telephone or facsimile within 24 hours of the time when the Permittee first learned of the occurrence of excess emissions including all available information from Condition XII.A.1.b below.
 - (2) Detailed written notification by submission of an excess emissions report within 72 hours of the notification pursuant to Condition XII.A.1.a. (1) above.
- b. The report shall contain the following information:
 - (1) Identity of each stack or other emission point where the excess emissions occurred;
 - (2) Magnitude of the excess emissions expressed in the units of the applicable emission limitation and the operating data and calculations used in determining the magnitude of the excess emissions;
 - (3) Date, time and duration, or expected duration, of the excess emissions;
 - (4) Identity of the equipment from which the excess emissions emanated;

- (5) Nature and cause of such emissions;
 - (6) If the excess emissions were the result of a malfunction, steps taken to remedy the malfunction and the steps taken or planned to prevent the recurrence of such malfunctions; and
 - (7) Steps taken to limit the excess emissions. If the excess emissions resulted from start-up or malfunction, the report shall contain a list of the steps taken to comply with the permit procedures.
2. In the case of continuous or recurring excess emissions, the notification requirements of this section shall be satisfied if the source provides the required notification after excess emissions are first detected and includes in such notification an estimate of the time the excess emissions will continue. Excess emissions occurring after the estimated time period, or changes in the nature of the emissions as originally reported, shall require additional notification pursuant to Condition XII.A.1 above.

[A.A.C. R18-2-310.01.C]

B. Permit Deviations Reporting

[A.A.C. R18-2-306.A.5.b]

The Permittee shall promptly report deviations from permit requirements, including those attributable to upset conditions as defined in the permit, the probable cause of such deviations, and any corrective actions or preventive measures taken. Prompt reporting shall mean that the report was submitted to the Director by certified mail, facsimile, or hand delivery within two working days of the time when emission limitations were exceeded due to an emergency or within two working days of the time when the owner or operator first learned of the occurrence of a deviation from a permit requirement.

C. Emergency Provision

[A.A.C. R18-2-306.E]

1. An “emergency” means any situation arising from sudden and reasonable unforeseeable events beyond the control of the source, including acts of God, that require immediate corrective action to restore normal operation, and that causes the source to exceed a technology-based emission limitation under the permit, due to unavoidable increases in emissions attributable to the emergency. An emergency shall not include noncompliance to the extent caused by improperly designed equipment, lack of preventative maintenance, careless or improper operation, or operator error.
2. An emergency constitutes an affirmative defense to an action brought for noncompliance with such technology-based emission limitations if Condition XII.C.3 is met.
3. The affirmative defense of emergency shall be demonstrated through properly signed, contemporaneous operating logs, or other relevant evidence that:
 - a. An emergency occurred and that the Permittee can identify the cause(s) of the emergency;
 - b. The permitted facility was being properly operated at the time;

- c. During the period of the emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emissions standards or other requirements in the permit; and
 - d. The Permittee submitted notice of the emergency to the Director by certified mail, facsimile, or hand delivery within two working days of the time when emission limitations were exceeded due to the emergency. This notice shall contain a description of the emergency, any steps taken to mitigate emissions, and corrective action taken.
- 4. In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.
 - 5. This provision is in addition to any emergency or upset provision contained in any applicable requirement.

D. Compliance Schedule

[ARS § 49-426.I.5]

For any excess emission or permit deviation that cannot be corrected with 72 hours, the Permittee is required to submit a compliance schedule to the Director within 21 days of such occurrence. The compliance schedule shall include a schedule of remedial measures, including an enforceable sequence of actions with milestones, leading to compliance with the permit terms or conditions that have been violated.

E. Affirmative Defenses for Excess Emissions Due to Malfunctions, Startup, and Shutdown

[A.A.C. R18-2-310]

1. Applicability

This rule establishes affirmative defenses for certain emissions in excess of an emission standard or limitation and applies to all emission standards or limitations except for standards or limitations:

- a. Promulgated pursuant to Sections 111 or 112 of the Act;
- b. Promulgated pursuant to Titles IV or VI of the Clean Air Act;
- c. Contained in any Prevention of Significant Deterioration (PSD) or New Source Review (NSR) permit issued by the U.S. EPA;
- d. Contained in A.A.C. R18-2-715.F; or
- e. Included in the permit to meet the requirements of A.A.C. R18-2-406.A.5.

2. Affirmative Defense for Malfunctions

Emissions in excess of an applicable emission limitation due to malfunction shall constitute a violation. When emissions in excess of an applicable emission limitation are due to a malfunction, the Permittee has an affirmative defense to a civil or administrative enforcement proceeding based on that violation, other than a judicial action seeking injunctive relief, if the Permittee has complied with the reporting requirements of A.A.C. R18-2-310.01 and has demonstrated all of the following:

- a. The excess emissions resulted from a sudden and unavoidable breakdown of process equipment or air pollution control equipment beyond the reasonable control of the Permittee;
- b. The air pollution control equipment, process equipment, or processes were at all times maintained and operated in a manner consistent with good practice for minimizing emissions;
- c. If repairs were required, the repairs were made in an expeditious fashion when the applicable emission limitations were being exceeded. Off-shift labor and overtime were utilized where practicable to ensure that the repairs were made as expeditiously as possible. If off-shift labor and overtime were not utilized, the Permittee satisfactorily demonstrated that the measures were impracticable;
- d. The amount and duration of the excess emissions (including any bypass operation) were minimized to the maximum extent practicable during periods of such emissions;
- e. All reasonable steps were taken to minimize the impact of the excess emissions on ambient air quality;
- f. The excess emissions were not part of a recurring pattern indicative of inadequate design, operation, or maintenance;
- g. During the period of excess emissions there were no exceedances of the relevant ambient air quality standards established in Title 18, Chapter 2, Article 2 of the Arizona Administrative Code that could be attributed to the emitting source;
- h. The excess emissions did not stem from any activity or event that could have been foreseen and avoided, or planned, and could not have been avoided by better operations and maintenance practices;
- i. All emissions monitoring systems were kept in operation if at all practicable; and
- j. The Permittee's actions in response to the excess emissions were documented by contemporaneous records

3. Affirmative Defense for Startup and Shutdown

- a. Except as provided in Condition XII.E.3.b below, and unless otherwise provided for in the applicable requirement, emissions in excess of an applicable emission limitation due to startup and shutdown shall constitute a violation. When emissions in excess of an applicable emission limitation are due to startup and shutdown, the Permittee has an affirmative defense to a civil or administrative enforcement proceeding based on that violation, other than a judicial action seeking injunctive relief, if the Permittee has complied with the reporting requirements of A.A.C. R18-2-310.01 and has demonstrated all of the following:
 - (1) The excess emissions could not have been prevented through careful and prudent planning and design;
 - (2) If the excess emissions were the result of a bypass of control equipment, the bypass was unavoidable to prevent loss of life, personal injury, or

severe damage to air pollution control equipment, production equipment, or other property;

- (3) The air pollution control equipment, process equipment, or processes were at all times maintained and operated in a manner consistent with good practice for minimizing emissions;
- (4) The amount and duration of the excess emissions (including any bypass operation) were minimized to the maximum extent practicable during periods of such emissions;
- (5) All reasonable steps were taken to minimize the impact of the excess emissions on ambient air quality;
- (6) During the period of excess emissions there were no exceedances of the relevant ambient air quality standards established in Title 18, Chapter 2, Article 2 of the Arizona Administrative Code that could be attributed to the emitting source;
- (7) All emissions monitoring systems were kept in operation if at all practicable; and
- (8) Contemporaneous records documented the Permittee's actions in response to the excess emissions.

- b. If excess emissions occur due to a malfunction during routine startup and shutdown, then those instances shall be treated as other malfunctions subject to Condition XII.E.2 above.

4. Affirmative Defense for Malfunctions During Scheduled Maintenance

If excess emissions occur due to a malfunction during scheduled maintenance, then those instances will be treated as other malfunctions subject to Condition XII.E.2 above.

5. Demonstration of Reasonable and Practicable Measures

For an affirmative defense under Condition XII.E.2 or XII.E.3 above, the Permittee shall demonstrate, through submission of the data and information required by Condition XII.E and A.A.C. R18-2-310.01, that all reasonable and practicable measures within the Permittee's control were implemented to prevent the occurrence of the excess emissions.

XIII. RECORD KEEPING REQUIREMENTS

[A.A.C. R18-2-306.A.4]

- A. The Permittee shall keep records of all required monitoring information including, but not limited to, the following:
 1. The date, place as defined in the permit, and time of sampling or measurements;
 2. The date(s) analyses were performed;
 3. The name of the company or entity that performed the analyses;

4. A description of the analytical techniques or methods used;
 5. The results of such analyses; and
 6. The operating conditions as existing at the time of sampling or measurement.
- B.** The Permittee shall retain records of all required monitoring data and support information for a period of at least 5 years from the date of the monitoring sample, measurement, report, or application. Support information includes all calibration and maintenance records and all original strip-chart recordings or other data recordings for continuous monitoring instrumentation, and copies of all reports required by the permit.
- C.** All required records shall be maintained either in an unchangeable electronic format or in a handwritten logbook utilizing indelible ink.

XIV. REPORTING REQUIREMENTS

[A.A.C. R18-2-306.A.5.a]

The Permittee shall submit the following reports:

- A.** Compliance certifications in accordance with Section VII of Attachment “A”.
- B.** Excess emission; permit deviation, and emergency reports in accordance with Section XII of Attachment “A”.
- C.** Other reports required by any condition of Attachment “B”.

XV. DUTY TO PROVIDE INFORMATION

[A.A.C. R18-2-304.G and -306.A.8.e]

- A.** The Permittee shall furnish to the Director, within a reasonable time, any information that the Director may request in writing to determine whether cause exists for revising, revoking and reissuing, or terminating the permit, or to determine compliance with the permit. Upon request, the Permittee shall also furnish to the Director copies of records required to be kept by the permit. For information claimed to be confidential, the Permittee shall furnish an additional copy of such records directly to the Administrator along with a claim of confidentiality.
- B.** If the Permittee has failed to submit any relevant facts or has submitted incorrect information in the permit application, the Permittee shall, upon becoming aware of such failure or incorrect submittal, promptly submit such supplementary facts or corrected information.

XVI. PERMIT AMENDMENT OR REVISION

[A.A.C. R18-2-318, -319, and -320]

The Permittee shall apply for a permit amendment or revision for changes to the facility which do not qualify for a facility change without revision under Section XVII, as follows:

- A.** Administrative Permit Amendment (A.A.C. R18-2-318);
- B.** Minor Permit Revision (A.A.C. R18-2-319); and
- C.** Significant Permit Revision (A.A.C. R18-2-320)

The applicability and requirements for such action are defined in the above referenced regulations.

XVII. FACILITY CHANGE WITHOUT A PERMIT REVISION

[A.A.C. R18-2-306.A.4 and -317]

- A.** The Permittee may make changes at the permitted source without a permit revision if all of the following apply:
1. The changes are not modifications under any provision of Title I of the Act or under ARS § 49-401.01(19);
 2. The changes do not exceed the emissions allowable under the permit whether expressed therein as a rate of emissions or in terms of total emissions;
 3. The changes do not violate any applicable requirements or trigger any additional applicable requirements;
 4. The changes satisfy all requirements for a minor permit revision under A.A.C.-R18-2-319.A; and
 5. The changes do not contravene federally enforceable permit terms and conditions that are monitoring (including test methods), record keeping, reporting, or compliance certification requirements.
- B.** The substitution of an item of process or pollution control equipment for an identical or substantially similar item of process or pollution control equipment shall qualify as a change that does not require a permit revision, if it meets all of the requirements of Conditions XVII.A and XVII.C of this Attachment.
- C.** For each change under Conditions XVII.A and XVII.B above, a written notice by certified mail or hand delivery shall be received by the Director and the Administrator a minimum of 7 working days in advance of the change. Notifications of changes associated with emergency conditions, such as malfunctions necessitating the replacement of equipment, may be provided less than 7 working days in advance of the change, but must be provided as far in advance of the change, as possible or, if advance notification is not practicable, as soon after the change as possible.
- D.** Each notification shall include:
1. When the proposed change will occur;
 2. A description of the change;
 3. Any change in emissions of regulated air pollutants; and
 4. Any permit term or condition that is no longer applicable as a result of the change.
- E.** The permit shield described in A.A.C. R18-2-325 shall not apply to any change made under this Section, other than implementation of an alternate to Conditions XVII.A and XVII.B above.
- F.** Except as otherwise provided for in the permit, making a change from one alternative operating scenario to another as provided under A.A.C. R18-2-306.A.11 shall not require any prior notice under this Section.

- G.** Notwithstanding any other part of this Section, the Director may require a permit to be revised for any change that, when considered together with any other changes submitted by the same source under this Section over the term of the permit, do not satisfy Condition XVII.A above.

XVIII. TESTING REQUIREMENTS

[A.A.C. R18-2-312]

- A.** The Permittee shall conduct performance tests as specified in the permit and at such other times as may be required by the Director.

B. Operational Conditions During Testing

Tests shall be conducted during operation at the maximum possible capacity of each unit under representative operational conditions unless other conditions are required by the applicable test method or in this permit. With prior written approval from the Director, testing may be performed at a lower rate. Operations during periods of start-up, shutdown, and malfunction (as defined in A.A.C. R18-2-101) shall not constitute representative operational conditions unless otherwise specified in the applicable standard.

- C.** Tests shall be conducted and data reduced in accordance with the test methods and procedures contained in the Arizona Testing Manual unless modified by the Director pursuant to A.A.C. R18-2-312.B.

D. Test Plan

At least 14 calendar days prior to performing a test, the Permittee shall submit a test plan to the Director in accordance with A.A.C. R18-2-312.B and the Arizona Testing Manual. This test plan must include the following:

1. Test duration;
2. Test location(s);
3. Test method(s); and
4. Source operation and other parameters that may affect test results.

E. Stack Sampling Facilities

The Permittee shall provide, or cause to be provided, performance testing facilities as follows:

1. Sampling ports adequate for test methods applicable to the facility;
2. Safe sampling platform(s);
3. Safe access to sampling platform(s); and
4. Utilities for sampling and testing equipment.

F. Interpretation of Final Results

Each performance test shall consist of three separate runs using the applicable test method. Each run shall be conducted for the time and under the conditions specified in the applicable standard. For the purpose of determining compliance with an applicable standard, the arithmetic mean of the results of the three runs shall apply. In the event that a sample is accidentally lost or conditions occur in which one of the three runs is required to be discontinued because of forced shutdown, failure of an irreplaceable portion of the sample train, extreme meteorological conditions, or other circumstances beyond the Permittee's control, compliance may, upon the Director's approval, be determined using the arithmetic mean of the results of the other two runs. If the Director or the Director's designee is present, tests may only be stopped with the Director's or such designee's approval. If the Director or the Director's designee is not present, tests may only be stopped for good cause. Good cause includes: forced shutdown, failure of an irreplaceable portion of the sample train, extreme meteorological conditions, or other circumstances beyond the Permittee's control. Termination of any test without good cause after the first run is commenced shall constitute a failure of the test. Supporting documentation, which demonstrates good cause, must be submitted.

G. Report of Final Test Results

A written report of the results of all performance tests shall be submitted to the Director within 30 days after the test is performed. The report shall be submitted in accordance with the Arizona Testing Manual and A.A.C. R18-2-312.A.

XIX. PROPERTY RIGHTS

[A.A.C. R18-2-306.A.8.d]

This permit does not convey any property rights of any sort, or any exclusive privilege.

XX. SEVERABILITY CLAUSE

[A.A.C. R18-2-306.A.7]

The provisions of this permit are severable. In the event of a challenge to any portion of this permit, or if any portion of this permit is held invalid, the remaining permit conditions remain valid and in force.

XXI. PERMIT SHIELD

[A.A.C. R18-2-325]

Compliance with the conditions of this permit shall be deemed compliance with all applicable requirements identified in the portions of this permit subtitled "Permit Shield". The permit shield shall not apply to minor revisions pursuant to Condition XVI.B of this Attachment and any facility changes without a permit revision pursuant to Section XVII of this Attachment.

XXII. PROTECTION OF STRATOSPHERIC OZONE

[40 CFR Part 82]

If this source becomes subject to the provisions of 40 CFR Part 82, then the Permittee shall comply with these provisions accordingly.

ATTACHMENT “B”: SPECIFIC CONDITIONS

Air Quality Control Permit No. 34304
for
STERIS, Inc

I. FACILITY WIDE CONDITIONS

- A. The Permittee shall have on site or on call a person that is certified in EPA Reference Method 9.
[A.A.C R18-2-306.A.3.c]
- B. At the time the compliance certifications required by Section VII of Attachment “A” are submitted, the Permittee shall submit reports of all monitoring activities required by Attachment “B” performed during the six month compliance term.
[A.A.C. R18-2-306.A.5.a]
- C. The maximum plant wide use of Ethylene Oxide (ETO) shall not exceed 2400 pounds per day and 438 tons in any rolling 12 month period.
[A.A.C 18-2-306.A.2]
- D. On a daily basis, Permittee shall keep records of the quantity of ETO used at the facility.
[A.A.C R18-2-306.A.3.c]
- E. On a monthly basis, Permittee shall keep rolling 12 month records of the ETO used at the facility.
[A.A.C R18-2-306.A.3.c]

II. BOILERS WATER HEATER AND OXIDIZER HEATER

A. Particulate Matter and Opacity

1. Emission Limitations/Standards

a. Opacity

The Permittee shall not cause to be discharged into the atmosphere from the gas fired boiler and water heater stack, any gases which exhibit greater than 15 percent opacity, as measured by EPA Reference Method 9.
[A.A.C R18-2-724.J]

b. Particulate Matter

The Permittee shall not cause, allow, nor permit the emission of particulate matter, caused by combustion of fuel, from any fuel-burning operation in excess of the amounts calculated by the following equation:

$$E = 1.02Q^{0.769}$$

where:

E = the maximum allowable particulate emissions rate in pounds-mass per hour.

Q = the heat input in million Btu per hour.

For the purposes of this condition, the heat input shall be the aggregate heat content of all fuels whose products of combustion pass through a stack or other outlet. The total heat input of all operating fuel-burning units at a plant or premises shall be used for

determining the maximum allowable amount of particulate matter which may be emitted.

[A.A.C. R18-2-724.B]

[A.A.C. R18-2-724.C.1]

B. Monitoring/Recordkeeping and Reporting

The Permittee shall report all six-minute periods in which the opacity of any plume or effluent exceeds 15 %.

[A.A.C R18-2-742.J]

C. Fuel Limitation

The Permittee shall burn only natural gas in the boilers, water heater and oxidizer heater.

[A.A.C R18-2-306.A.2]

D. Permit Shield

Compliance with this Condition shall be deemed compliance with A.A.C. R18-2-724.B and A.A.C. R18-2-724.J as of the date of issuance of this permit.

[A.A.C. R18-2-325]

III. STERILIZATION CHAMBERS AND AERATION CHAMBERS

A. Emission Limitations/Standards

1. The Permittee shall not cause or allow to be discharged to the atmosphere from the exhaust of the catalytic oxidizer, ETO in excess of 0.34 ppm.

[A.A.C R18-2-306.A.2]

2. The Permittee shall reduce ETO emissions to the atmosphere by at least 99 percent from each sterilization chamber vent. The emission limitations apply during sterilization operation. The emission limitations do not apply during periods of malfunctions.

[40 CFR 63.362(b)]

[40 CFR 63.362(c)]

3. The Permittee shall reduce ethylene oxide (ETO) emissions to the atmosphere from the aeration room vent to a maximum concentration of 1ppmv or by at least 99 percent, whichever is less stringent, from each aeration room vent. The emission limitations apply during sterilization operation. The emission limitations do not apply during periods of malfunctions.

[40 CFR 63.362(b)]

[40 CFR 63.362(d)]

B. Air Pollution Control Requirements

1. The Permittee shall operate, and maintain (in accordance with manufacture's specifications) a Chemrox Deoxx scrubber to remove ETO from the sterilization chamber evacuation gases.

[Condition III.A of Installation Permit # 4405-95]

[Material permit conditions are indicated by double underline]

[A.A.C.R18-2-331.A.3.e]

2. The Permittee shall operate, and maintain (in accordance with manufacture's specifications) a Chemrox Deoxx scrubber to remove ETO from the hot cell exhaust gases.

[Condition III.A of Installation Permit # 4405-95]

[Material permit conditions are indicated by double underline]

[A.A.C.R18-2-331.A.3.e]

3. The Permittee shall operate, and maintain (in accordance with manufacturer's specification) a

Donaldson catalytic oxidizer to remove ETO from the plant exhaust streams.

[Condition III.A of Installation Permit # 4405-95]

[A.A.C R18-2-331.A.e]

[Material permit conditions are indicated by double underline]

C. Operational Limitations

1. The Permittee shall not operate each sterilization chamber for more than three sterilization cycles per day. [A.A.C R18-2-306.A.2]
2. The Permittee shall establish as an operating limit either, the maximum ethylene glycol concentration using the procedures in 40 CFR 63.365(e)(1) or the maximum liquor tank level using the procedures in 40 CFR 63.365(e)(2). [40 CFR 63.362(2)]
3. The Permittee shall operate the catalytic oxidizer at the minimum operating temperature of 280 degree Fahrenheit as specified by the manufacturer. [40 CFR 63.363(b)(3)]

D. Monitoring/Recordkeeping/Reporting Requirements

1. The Permittee shall comply with monitoring requirements 40 CFR 63.8(a)(1), 40 CFR 63.8(a)(2), and 40 CFR 63.8(a)(4), as specified in the applicability table in 40 CFR 63.360, Subpart O. [40 CFR 63.364(a)(1)]
2. All monitoring equipment shall be installed such that the representative measurements of emissions or process parameters from the facility are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system. [40 CFR 63.364(a)(2)]
3. When the oxidation unit is operated, the Permittee shall continuously monitor and record the oxidation temperature at the outlet to the catalyst or at the exhaust point from the thermal combustion chamber using a temperature monitor as described in 40 CFR 63.364(c)(4). [40 CFR 63.364(c)]
 - (a) For the sterilization chamber vent, from 15 minutes or shorter period temperature values, a data acquisition system for the temperature monitor shall compute and record average oxidation temperature. [40 CFR 63.364(c)]
 - (b) Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature. [40 CFR 63.364(c)]
 - (c) The Permittee shall calibrate, operate, and maintain a temperature monitor accurate to within $\pm 5.6^{\circ}\text{C}$ to measure the oxidation temperature. The Permittee shall verify the accuracy of the temperature monitor twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measure device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested.

[40 CFR 63.364(c)(4)]

[Material permit conditions are indicated by double underline]

[A.A.C R18-2-331.A.3.c]

4. Measure and record once per week the level of the scrubber liquor in the recirculation tank. The owner or operator shall install, maintain, and use a liquid level indicator to measure the scrubber liquid tank level (i.e., a marker on the tank wall, a dipstick, a magnetic indicator, etc.). Monitoring is required during a week only if the scrubber unit has been operated.
[40 CFR 63.364(b)(2)]
[Material permit conditions are indicated by double underline]
[A.A.C.R18-2-331.A.3.c]
6. The Permittee shall maintain records of the maintenance records and downtime associated with the ethylene oxide scrubber.
[40 CFR 63.367(d)]
7. The Permittee shall comply with all the reporting requirements in 40 CFR 63.10(a), (d), (e), and (f) of Subpart A as specified in the applicability table in 40 CFR 63.360, Subpart O. These reports shall be made to the EPA Administrator and ADEQ Director.
[40 CFR 63.366(a)]
8. Required reports may be sent by U.S. mail, fax, or by another courier.
- (a). Submittal sent by U.S. mail, fax, or by courier shall be post marked on or before the specified date.
[40 CFR 63.366(a)(1)(i)]
- (b). Submittals sent by other methods shall be received by the Director on or before the specified date.
[40 CFR 63.366(a)(1)(ii)]
9. If acceptable to both the Director and the Permittee, reports may be submitted on electronic media.
[40 CFR 63.366(a)(2)]
10. All excess emissions and monitoring system performance reports and all summary reports shall be delivered or postmarked within 30 days following the end of each calendar half as appropriate. Written reports of excess emissions or exceedances of the process or control system parameters shall include all information required in 40 CFR 63.10.c (5) through (13) and information from any calibration tests in which the monitoring equipment is not in compliance with PS-9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no excess emissions or exceedances have occurred, or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.
[40 CFR 63.366.a.3]
11. The Permittee shall fulfill all notification requirements in 40 CFR 63.9, as specified in the applicability table in 40 CFR 63.360, Subpart O.
[40 CFR 63.366(c)]
12. The Permittee shall comply with the recordkeeping requirements 40 CFR 63.10(b) and (c) according to the table in 40 CFR 63.360, Subpart O
[40 CFR 63.367(a)]
13. The Permittee shall maintain the most recent 2 years of records onsite or shall be accessible to an inspector while onsite.
[40 CFR 63.367(a)]
14. The Permittee shall maintain the records in hard copy or computer-readable form including,

but not limited to, on paper, microfilm, computer, computer disk, magnetic tape, or microfiche.

[40 CFR 63.367(a)]

15. The Permittee shall maintain records of the compliance test, data analysis, and if catalyst is replaced, proof of replacement.

[40 CFR 63.367(d)]

E. Testing Requirements

1. The Permittee shall comply with the performance testing requirements in § 63.7 of subpart A as specified in the applicability table in 40 CFR 63.360, Subpart O.

[40 CFR 63.365.a]

2. The Permittee shall conduct performance tests once per year using Reference Method 18 to show compliance with emission limits specified in Condition III.A.

[A.A.C R18-2-312]

F. Permit Shield

Compliance with this section shall be deemed compliance with 40 CFR 63.3, 40 CFR 63.362.b, 40 CFR 63.364.a.1, 40 CFR 63.364.a.2, 40 CFR 63.364.b.2, 40 CFR 63.364.c, 40 CFR 63.364.c.4, 40 CFR 63.365.a., CFR 63.366.a.1.i , 40, 40 CFR 63.366.a.1.ii, 40 CFR 63.366.a.2, 40 CFR 63.366.a.3, 40 CFR 63.366.c, 40 CFR 63.367.a, and 40 CFR 63.367.d, as of the date of permit issuance.

[A.A.C R18-2-325]

IV. FUGITIVE EMISSIONS

Particulate Matter and Opacity

A. Operational Requirements for Open Areas, Roadways & Streets, Storage Piles, and Material Handling

1. Permittee shall not cause, allow, or permit visible emissions from any non-point source in excess of 40 percent opacity limited in accordance with the Arizona Testing Manual, Reference Method 9.

[A.A.C.R18-2-612.A.4]

2. Permittee shall employ the following reasonable precautions to prevent excessive amounts of particulate matter from becoming airborne:

- a. All roads, parking lots, and any other areas with frequent vehicular traffic shall be paved. Service or maintenance roads that are used infrequently shall be graveled or otherwise treated with dust suppressants, adhesive soil stabilizer, or wetting agents to control dust. Infrequently used roads include those which provide access to and around the brine disposal pond, the fuel gas metering station, the transmission lines, and the construction heavy equipment haul road.

[A.A.C. R18-2-406.A.4]

- b. Use approved dust suppressants, adhesive soil stabilizer, paving, covering, detouring, or wetting agents on, or bar access to open areas during construction operations, repair operations, demolition activities, clearing operations, and leveling operations, or when any earth is moved or excavated.

[A.A.C. R18-2-604.A]

- c. Use approved dust suppressants, temporary paving, detouring or wetting agents when

a roadway is repaired, constructed, or reconstructed.

[A.A.C. R18-2-605.A]

B. Monitoring, Recordkeeping, and Reporting Requirements

Open Areas, Roadways & Streets, Storage Piles, and Material Handling

The Permittee shall maintain records of dates and type of control measures adopted pursuant to Specific Condition IV.A.2 of Attachment “B.”

[A.A.C. R18-2-306.A.3.c]

C. Permit Shield

Compliance with this section shall be deemed compliance with A.A.C.R18-2-604.A, A.A.C.R18-2-605.A, and A.A.C.R18-2-612 as of the date of permit issuance.

[A.A.C.R-18-325]

V. OTHER PERIODIC ACTIVITIES

A. Abrasive Blasting

1. Opacity

- a. The Permittee shall not cause, allow, or permit visible emissions from sandblasting or other abrasive blasting operation in excess of 20 percent opacity limit.

[A.A.C.R18-2-702.B]

- b. The Permittee shall not cause or allow sandblasting or other abrasive blasting without minimizing dust emissions to the atmosphere through the use of good modern practices. Good modern practices include:

- (1) Wet blasting;
- (2) Effective enclosure with necessary dust collecting equipment; or
- (3) Any other method as approved by the Director.

[A.A.C.R18-2-726]

2. Monitoring, Recordkeeping and Reporting Requirements

Each time an abrasive blasting project is conducted in an area open to the atmosphere, the Permittee shall log in ink or in an electronic format, a record of the following:

- a. The date the project was conducted;
- b. The duration of the project; and
- c. Type of control measures employed.

[A.A.C.R18-2-306.A.3.c]

3. Permit Shield

Compliance with conditions of this part shall be deemed compliance with A.A.C.R18-2-702.B and A.A.C.R18-2-726.

[A.A.C.R18-2-325]

B. Spray Painting

Volatile Organic Compounds

1. Emission Limits and Standards

- a. The Permittee shall not conduct or cause to be conducted any spray painting operation without minimizing organic solvent emissions. Such operations other than architectural coating and spot painting, shall be conducted in an enclosed area equipped with controls containing no less than 96 percent of the overspray.

[A.A.C.R18-2-727.A]

- b. The Permittee shall not employ, apply, evaporate, thin, dilute or dry any architectural coating photochemically reactive solvents for industrial or commercial purpose.

[A.A.C.R18-2-727.B]

- c. For purposes of parts b and c of this section, a photochemically reactive solvent shall be any solvent with an aggregate of more than 20 percent of its total volume composed of the chemical compounds classified in paragraphs (1) through (3) of this subsection, or which exceeds any of the following percentage composition limitations, referred to the total volume of solvents:

- (1) A combination of the following types of compounds having an olefinic or cycle-olefinic type of unstauration-hydrocarbons, alcohols, aldehydes, esters, ethers, ethers, or ketones: five percent.
- (2) A combination of aromatic compounds with eight or more carbon atoms to the molecule except ethylbenzene: eight percent
- (3) A combination of ethylbenzene, ketones having branched hydrocarbons structures, trichloroethylene or toluene: 20 percent.

[A.A.C.R18-2-727.C]

- d. Whenever any organic solvent or any constituent of an organic solvent may be classified from its chemical structure into more than one of the groups or organic compounds described in subsection c(1) through c(3) above, it shall be considered to be a member of the group having the least allowable percent of the total volume of solvents.

[A.A.C.R18-2-727.D]

- e. The Permittee shall not dispose by evaporation more than 1.5 gallons of photochemically reactive solvent in any one day. [SIP Provision R9-3-527.C]
- f. Visible emissions from spray painting operations shall not have opacity greater than 20 percent opacity, measured in accordance with EPA Reference Method 9.

[A.A.C.R18-2-702.B]

2. Monitoring, Recordkeeping, and Reporting Requirements

- a. Each time a spray painting project is conducted, the Permittee shall log in ink or in an electronic format, a record of the following: [A.A.C.R18-2-306.A.3.c]
 - i. The date the project was conducted;
 - ii. The duration of the project;
 - iii. Type of control measures employed; and
 - iv. Material Safety Data Sheets for all paints and solvents used in the project.
- b. Architectural coating and spot painting projects shall be exempt from the recordkeeping requirements.

3. Permit Shield

Compliance with conditions of this part shall be deemed compliance with SIP Provision R9-3-527.C, A.A.C.R18-2-727 and A.A.C.R18-2-702.B.

[A.A.C.R18-2-325]

C. Mobile Sources

1. Classification

The requirements of this condition are applicable to mobile sources which either move while emitting air contaminants or are frequently moved during the course of their utilization but are not classified as motor vehicles, agricultural vehicles, or are agricultural equipment used in normal farm operations. Mobile sources shall not include portable sources as defined in A.A.C. R18-2-101.87.

[A.A.C. R18-2-801]

2. Roadway and Site Cleaning Machinery

Permittee shall not cause, allow or permit to be emitted into the atmosphere from any roadway and site cleaning machinery smoke or dust for any period greater than ten consecutive seconds, the opacity of which exceeds 40 percent. Visible emissions when starting cold equipment shall be exempt from this requirement for the first ten minutes.

[A.A.C. R18-2-804.A]

3. Permit Shield

Compliance with the conditions of this part shall be deemed compliance with A.A.C.R18-2-801 and A.A.C.R18-2-804.A. [A.A.C.R18-2-325]

D. Non-Vehicle Air Conditioner Maintenance and/or Services

1. The Permittee shall comply with the applicable requirements of 40 CFR 82 - Subpart F (Protection of Stratospheric Ozone - Recycling and Emissions Reduction). [40 CFR 82, Subpart F]
2. Permit Shield
Compliance with the conditions of this Part shall be deemed compliance with 40 CFR 82, Subpart F, as of the date of permit issuance. [A.A.C.R18-2-325]

ATTACHMENT "C": PROCESS AND CONTROL EQUIPMENT LIST

Air Quality Control Permit No. 34304

Equipment Type	Manufacturer	Model	Serial Number	Equipment ID Numbers	Nominal Rating	Date of Commercial Operation/ Manufacture
Boiler	Rite Engineering & Mfg. corp.	25	89-21968	EO Storage	250,000 Btu	1989
Boiler	Rite Engineering & Mfg. corp.	25-S	89-21969	Backup	250,000 Btu	1989
Boiler	Rite Engineering & Mfg. corp.	85-S	90-22076	Main	850,000 Btu	1990
ETO Sterilization Chambers	Vacudyne	N/A	J88-39/J88-59	J88-39/J88-59	N/A	N/A
ETO Scrubbers	DEOXX	120-25-18ez	00-12343-45	N/A	N/A	N/A
ETO Degassing Chambers	CHEMROX	N/A	NONE	#1,#2,#3,#4	N/A	N/A
Catalytic Oxidizer with heater	DONALDSON	626P6533	IG436752	N/A	N/A	1997